3 Integrated Safety, Environmental, Quality Assurance, and Safeguards and Security

A key component of the successful project is that safety, health, environmental, and quality issues are addressed early in a project's lifecycle and fully integrated into all project activities. The responsibility for safety, health, environment, and quality is a line management responsibility, owned by the entire IPT, starting with the PM. An Integrated Safety Management System (ISMS) is most effective when developed early and implemented throughout all project phases. ISMS is designed to ensure that safety basis, environmental protection, and worker and public safety is appropriately addressed in the planning and performance of any task. The fundamental premise of Integrated Safety Management (ISM) is that accidents are preventable through early and close attention to the planning, design, and physical execution of a project. Early stakeholder involvement in the planning and execution of a project, utilizing appropriately revised and approved standards is the norm. During the Initiation and Definition phases, the project has the unique opportunity to eliminate or minimize hazards, and incorporate cost-effective accident prevention and mitigative features. This includes taking a fresh look at the reference design to provide safety through design. Implementation of safety, health, environmental protection, and quality is be fully integrated based on principles, acquisition and project plans, and procedures. Throughout this Manual, the term safety encompasses protection of the public, the workers, and the environment. Quality and safety are to be integrated into the project management programs along with safety, health, and environmental protection program from the very beginning. This section first discusses integration of safety, health, environmental protection; followed by an adherence to quality.

3.1 Safety

A primary and continuous responsibility of project management is safety. This includes project plans and safety of project personnel, including those that will operate or maintain the facility, or that could otherwise be affected by the decisions made during the project planning, design, construction, and testing stages. This responsibility begins at the time a project or remedial action is planned and continues until the project or remedial action is completed. As the PM develops and maintains project baselines, the focus is on providing a safe, quality design.

Department Policy, DOE P 450.4 requires that safety management systems be used to systematically integrate safety into management and work practices at all levels so that missions are accomplished while protecting the public, the worker, and the environment. Integrated Safety Management (ISM) is required as part of DOE management of projects. As stated in DOE P 450.4, *Safety Management System Policy*,

> "This is to be accomplished through effective integration of safety management into all facets of work planning and execution. In other words, the overall management

of safety functions and activities becomes an integral part of mission accomplishment."

This policy requires that ISM functions and principles apply to all project and remedial action activities through all phases of these efforts. Ensuring adequate protection of the public, the workers, and the environment is an essential activity of the IPT, including project planning, design, technology development, construction, testing and turnover, and facility disposition. Each of these key areas is discussed in later subsections.

Project management, in using ISM, ensures that work processes related to planning and engineering are executed with attention to safety; and that work processes related to research, development, testing, use of hazardous materials, and construction techniques are executed with proper controls. This section will describe how ISM functions and principles are to be applied to the execution of a DOE project during each of its stages.

DOE is committed to conducting all work on its projects so that missions can be accomplished with adequate controls in place to protect workers, the public, and the environment. For those facilities that contain, or will contain, hazardous materials, continuous development and integration of safety analysis as an integral part of design is required. In other words, the fulfillment of safety functions by systems and structures becomes an integral part of fulfillment of project and mission functions.

The ISMS, along with the basic assumptions regarding quality and the specific requirements for the project, provide a framework under which the PEP and lower-tier documents such as implementation plans and procedures are developed. If the project is covered by an existing DOE site ISMS, then that governing site ISMS should be implemented within the project. If an existing ISMS can be used or modified to accommodate the project, then it is recommended that the project implement the site program through the PEP. If the project includes multiple companies, additional ISMS documentation may have to be developed to demonstrate organizational compliance with the specific project ISMS requirements.

3.1.1 Integrated Safety Management System

An ISMS is a system designed to ensure that environmental, worker, and public safety is appropriately addressed in the performance of any task. A fundamental premise of ISM is that accidents are preventable through early and close attention to safety, design, and operation, and with substantial stakeholder involvement in teams that plan and execute the project, based on appropriate standards. The ISMS consists of the objective, the guiding principles, the core functions, the mechanisms of implementation, clear responsibilities for implementation, and implementation. As such, an ISMS is characterized by a management system's ability to implement the seven guiding principles and five core management functions using the key implementing factors as described below.

To implement ISMS, the project needs to have a commitment to a standards-based safety program. Articulation of these objectives and principles is important, but not sufficient, to achieve effective safety management. The challenge to establishing a standards-based safety approach in a project is to provide the rigor associated with the standards, yet provide the flexibility to apply a hazards-based tailored approach to defining the requirements. ISMS, as an integral part of project management, ensures that work processes related to design, testing, and construction are planned and executed with proper controls and with appropriate attention to safety.

The successful safety system functions effectively within safety mandates, considering budget and resource limitations. It enables tailoring so that hazards are identified and controlled, yet not burden project phases with inflexible, prescriptive controls that needlessly inflate costs and constrain the project, but do not enhance safety. Thus, tailoring within project management functions (planning, analyzing hazards, establishing controls, performing tasks, assessing implementation, and providing feedback) will enable tasks to be managed at the appropriate levels. In effect, management systems function to optimize task planning and performance to enable those closest to the task—those who perform the task, those who manage or supervise the task, and those who will be affected by the results of the task—to plan and assume responsibility for it.

To assure that planning and implementation provides a materiel asset that facilitates safe operation and will not have open safety issues at project closeout, safety and environmental issues need to be identified and addressed early. Proper ISMS implementation ensures that the planning, design, and physical work are performed with proper attention to potential hazards, regardless of the type of activity being performed.

3.1.2 Integrated Safety Management Through Design

Addressing safety issues early ensures that plans and designs for safety are integrated into the project. The goal is to ensure that safety is “designed in” early instead of “added on” later with increased cost and decreased effectiveness. Safety through design is not just meeting the specified safety requirements in the design; it is the project team taking specific proactive measures regarding safety. This includes making design changes to eliminate hazards, minimize hazards, mitigate consequences, and preclude events that could release the hazard. Addressing hazards with a safety-through-design approach does not always require that systems, structures, or components be added that will prevent or mitigate the releases. Rather, it may involve removing or moving systems or changing design approaches that result in a safer facility and improved operations. It may also result in fewer safety class and safety significant controls being required in the final design.

For nuclear facilities, the recognition of anticipated hazards in the facility design requires special considerations. DOE has established the Safety Analysis Report (SAR) or the Hazards Analysis Report (HAR) as the preferred method for authorizing operation for its most hazardous facilities. The SAR also provides a critical feedback mechanism for the project. To assure integration of safety and design, the documents that support SAR preparation (e.g., Hazards Analysis Document, Fire Hazards Analysis, Emergency Response evaluations, etc.) need to be initiated early and developed along with the design. ISM provides the framework to provide continuous coordination between these two activities as necessary throughout the design process to ensure the final design meets both mission and safety requirements.

3.1.2.1 Objective

The project objective is to systematically integrate safety into management, planning, and work practices at all levels and at all stages of the project so that missions are accomplished while assuring protection for the public, the worker, and the environment. This is accomplished through effective integration of safety management into all facets of project planning and execution, such that the overall management of safety functions and activities become an integral part of the project. The ISMS description needs to address the project roles and responsibilities for changing project teams and contracts during each project phase. Due to the changing need in each area, the PM needs to assure that appropriate coverage is provided on the IPT from these organizations on the IPT for each phase of the project.

3.1.2.2 Guiding Principles

The ISM Guiding Principles and Core Functions provided in DOE P 450.4, Safety Management System Policy are required to be applied to ensure that safety is integrated into all phases of project planning and implementation. These principles as they relate specifically to project management are:

- Line Management Responsibility for Safety: Project management is directly responsible for ensuring the facility structures, systems, and components, or the remedial activities recovery actions, protect the public, the workers, and the environment.
- Clear Roles and Responsibilities: Clear and unambiguous lines of authority and responsibility for ensuring safety is integrated into designs and remedial actions and are established and maintained at all organizational levels within the Department, the project, contractors, and suppliers.
- Competence Commensurate with Responsibilities: Project personnel need to possess the experience, knowledge (including project procedures and controls), skills, and abilities that are necessary to discharge their responsibilities. Materiel assets, including those that contain or will contain hazardous material, require specific competencies including hazard analysis, accident analysis, safety system design, QA, facility construction, and facility operation and maintenance, which are tailored based on risk.
- Balanced Priorities: Programmatic, operational, and safety requirements need to be effectively fulfilled by facility features. Protecting the public, the workers, and the environment is a priority for all design, construction, modification, or remediation.
- Identification of Safety Standards and Requirements: The PM should assure the hazard evaluation process is initiated early and continued throughout the project. Before detailed design is performed, the associated hazards are to be evaluated and an agreed-

upon set of safety standards and requirements established which, if properly implemented, will provide adequate assurance that the public, the workers, and the environment are protected from adverse consequences of facility operation.

- Engineered Controls Tailored to the Function Being Designed or Performed: Engineering controls that are designed to prevent and mitigate hazards are tailored to the facility function or the remedial activity and the associated hazards.
- Approval to Proceed: Reviews (project, design, and independent) are performed to verify that safety has been adequately integrated into the evolving design before approval is given to proceed to the next design phase, procurement, construction, or operation.

3.1.2.3 Core Functions

The expectations for an integrated safety management approach can be described by a successive set of actions or activities. This management system is modeled by the five core safety management functions, adopted in Table 3-1 to reflect the design process:

Table 3-1. ISMS Operations to Project's Relationships

ISMS Operations		ISMS Projects
Define the Work	↔	Requirements and Technical Scope of Work
Analyze the Hazards	↔	Analyze Potential Hazards
Develop and Implement Hazard Controls	↔	Develop Design Controls/ Requirements
Perform Work within Controls	↔	Perform Work/Design
Assessment and Feedback	↔	Review, Feedback, Improvement and Validation

The five core safety function relationships are illustrated in Figure 3-1. Although the arrows indicate a general direction, these are not independent, sequential functions.

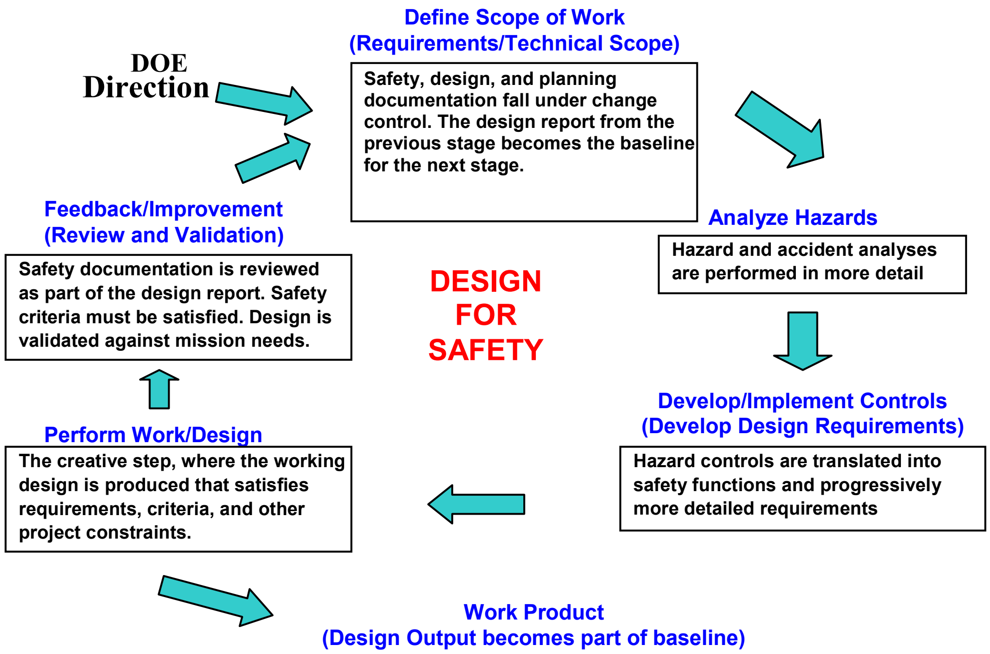

Figure 3-1. Safety Aspects in a Typical Design Stage

Requirements and Technical Scope of Work

During each design stage, safety and design planning/documentation are progressively developed, become more detailed and are placed under change control. The design/plan from a previous stage becomes the baseline for the next stage.

Analyze Potential Hazards

Hazards and accidents are analyzed in progressively more detail in each stage. Safety analysts work closely with project engineers to develop a common understanding of the facility, systems and processes, possible hazards including hazardous materials, and the envisioned operation of the facility.

Develop Controls/Requirements

Hazard controls are translated into safety functions and progressively more detailed requirements affecting the project. Hazard analysis and accident analysis (if needed) will identify aspects of process and design necessary for safety, as well as systems that are dedicated to the fulfillment of necessary safety functions. In addition to physical controls, administrative controls required to provide or support the safety functions are identified.

External constraints, such as laws, rules, codes, standards, and contracts are examined for their applicability. Relevant criteria and requirements are extracted and entered into the project-specific design manuals.

Perform Work/Design/Plan

While not always visible as a discrete function in the process, design, and planning is the "creative" function of the process where a working design/plan that will satisfy requirements, criteria, and other constraints is developed. The working designs/plans are committed to "paper" and assembled into a package that constitutes the output of this stage, and is approved under configuration (change) control.

Review, Feedback, Improvement and Validation

This function consists of unscheduled (lower-tiered) reviews and (upper-tiered) scheduled critical decision reviews. Safety design is specifically included in the review, and safety review criteria are established for each stage. The review criteria for earlier stages are reexamined in each stage to ensure corrective actions from prior reviews have been taken and those changes have not invalidated earlier reviews. For nuclear facilities, general criteria are identified for each stage of design and construction in the detailed description of each stage given in the Practices. These criteria should be adapted and used, as relevant, for specific projects. The process of developing the safety documentation (e.g., SAR) provides a valuable feedback and improvement mechanism for this function.

3.1.3 ISMS Implementation for Project Management Activities

As previously described, ISM is an essential part of all project activities. The guiding principles and core functions of ISM should be used throughout each project. This section discusses applying ISM to key project activities: planning, design, technology development, construction, and facility disposition. To assure project execution planning appropriately addresses the interactions between the seven principles and five core functions, a crosswalk of guiding principles and core functions against implementation within the procedures and practices is helpful. This crosswalk provides a valuable tool for the PM and IPT to assure the implementation procedures address ISM functions and principles. A continuing focus of ISMS implementation is to assure that the stakeholders are fully and appropriately involved with the current phase of the project as well as detailed planning for the next phase.

3.1.3.1 Project Planning

Project planning should include early identification of potential hazards. For nuclear facilities, activities recommended in DOE G 420.1-1, Section 2 will be conducted at the appropriate stages of the design. The PEP should address ISM implementation within the project. A principle of project planning is that it be routinely evaluated to assure that all areas are fully integrated and that changes in one area are reflected in other areas. A valuable safety communications tool for projects with hazardous facilities (those categorized above Hazard Category 2), is the lower-tier safety analysis and documentation plan. The plan may be used to communicate the level of safety documentation that will be available at each critical decision point in the project. Early agreement by both the project and regulating body on the level of safety documentation by phase, not only supports project planning, but minimizes regulatory issues later in the project. The Practices provide an example of one of these plans and the level of documentation required for a relatively complex facility. For small, less complicated work scopes, safety planning may be effectively covered in the PEP.

3.1.3.2 Integrating Safety with Design

Delivering a facility or a modification that can meet its mission requirements while maintaining the safety of the public, workers, and the environment is essential for a successful project. For those facilities that contain, or will contain, hazardous materials, continuous development and integration of the safety analysis as an integral part of design is required. This is accomplished using ISM within design as described in Section 3.1.2. The task of developing the safety basis for the facility often drives design and operational requirements. The early integration of safety and design permits the development of timely and cost-effective solutions from the start, rather than as a crisis backfit at the end of the project. Providing a design that only meets all of the specified safety requirements may not be adequate to implement a safety-through-design approach.

3.1.3.3 Project Authorization

During the project phase there are clear, top-tier project hold points based on risk or hazards, for which an authorization to proceed is required. These top-tier project hold points are identified on the project's integrated schedule. Safety and environmental documentation support each of these authorization points. The authorization basis for the design phase for facilities with a DOE-STD-1027 categorization of HC-3 or higher will include a Preliminary Documented Safety Analysis (PDSA)/Preliminary Safety Analysis Report (PSAR), the SER, and the feedback from independent design reviews. Authorization for facilities below HC-3 is based on a like document (e.g., Auditable Safety Analysis), which may be covered as part of a Health and Safety Plan (HASP). The results from these elements should be used to develop the basis for authorizing and completing design work. During the Execution phase, adherence to the approved PDSA/PSAR (or like documents) and enforcement to the PDSA/PSAR/SER requirements are key elements for authorizing construction work. Finally, the authorization basis for the startup activities should be completing the SAR/DSA/SER required to satisfy DOE issuance of an approved DSA/FSAR. Each of these authorizing documents (and the ISM description) need to be updated periodically (typically, at least annually) as a result of technical changes, budget changes, feedback from reviews, and execution/closeout issues; and reflect the development of the DSA/FSAR which only occurs in the later phases of new facility development. Hold points should be implemented at a lower "task" level to assure that proper attention has been placed on each of the potentially affected areas prior to these project critical decision points.

3.1.4 Safety Documentation and Project Support

Timely development of safety documentation is critical to project implementation. As presented in Chapter 2, Figure 2-2 depicts the major stages of the project and the documentation needed to support each stage.

A key project element is the alignment of the requirements, the documentation, the facility, and the work practices associated with the facility throughout all project phases.

Critical roles for safety, following the design phase, are construction or remediation safety, testing and turnover activities, and ultimately, safety for the operations phase, which is not covered in this manual.

3.1.4.1 Safety in Technology Development and Demonstration Activities

Any activities associated with tests, experiments, proof-of-principle or technology development related to a project will also be carried out using the guiding principles and core functions of ISM according to DOE P 450.4. These activities are to be adequately planned, have hazards analyzed and controls implemented, be performed within controls, and have a review and feedback function.

3.1.4.2 Construction/Remediation Safety

Construction/remediation safety is best implemented using the five core functions and the seven guiding principles of DOE P 450.4 and its implementing guide. To assure cost-effective implementation, plans need to be developed early as part of project planning and documentation. Hazards are to be analyzed and appropriate controls established to protect workers during the construction phase. These controls should be those specified by OSHA, plus any others needed to ensure safety. Safety programs then ensure that construction activities are performed within controls. Finally, review mechanisms verify appropriate implementation of the construction safety program, and that the final project meets all requirements.

Preparation and use of installation/assembly procedures is an example of a valuable control. These procedures typically identify the methods of erection, special tooling/rigging, hold points and acceptance criteria. This planning/documentation ensures the task is thoroughly evaluated prior to proceeding. Involvement of all affected functions in the preparation of these procedures minimizes potential issues during construction.

Projects involving facility disposition activities should also use the guidance in DOE-STD-1120-98, “Integration of Environment, Safety, and Health into Facility Disposition Activities.”

3.1.4.3 Testing, Commissioning, and Turnover Safety

Testing, commissioning, and turnover safety is best implemented using the five core functions and the seven guiding principles of DOE P 450.4 and its implementing guide During this phase, hazards are to be identified and evaluated, and proper controls established. Of particular importance are hazards associated with stored energy (pressure, temperature), electrical, fluid flow, and operating equipment. Of critical importance is controlling ownership of the facility (or portions thereof) during this phase. Knowing which portions of the facility have been turned over to operations and which portions have not is critical to maintaining safety during turnover. If a phased turnover is planned, special attention needs to be given to those structures, systems, and components that are in operation, and the interfaces with non-impacting structures, systems, and components.

3.2 Environment

The principle for environmental integration is that PMs are committed to being stewards of the environment and execute projects in an environmentally sound and responsible manner. The scope of DOE projects often involves handling, treating, storing, transporting, or disposing of hazardous, toxic, or radioactive material or waste. DOE is committed to complying with applicable environmental laws and regulations, and for being responsible in preserving and improving the quality of the environment. DOE demonstrates this commitment by integrating environmental safety, including pollution prevention, waste minimization, and resource conservation activities, into all DOE projects. DOE also applies a tailored approach to EM to ensure a cost-effective, value-added approach to complying with environmental requirements and concerns. A key principle is that projects conduct all activities in a manner appropriate to the nature, scale, and environmental impacts of these activities, while maintaining compliance with applicable federal and state legislation and regulations. Specific implementation practices and requirements are described in Section 3.2.2.

3.2.1 Background

International Standards Organization (ISO) 14001 principles have been effectively used by DOE sites and projects to implement an EM system as required by Executive Order 13148. ISO 14001 defines a framework for the EM system associated with most DOE projects. The system is composed of the elements of an organization's overall management structure that address the immediate and long-term impact on the environment of its products, services, and processes.

3.2.2 Environmental Protection and Compliance

Each DOE project is to be implemented under a written EM process to anticipate and meet growing environmental performance expectations, and to ensure ongoing compliance with regulatory requirements. This management process may either be facility/project specific or a site wide management system. EM processes are discussed in Executive Order 13148, "Greening the Government Through Leadership in Environmental Management" and DOE G 450.4-1A, "Integrated Safety Management System Guide." The environmental baseline for a project is to be established prior to any work being performed at the work site. For ER projects, the environmental baseline is typically provided as an integral part of the baseline risk assessment. Environmental baseline monitoring may be required considerably before beginning construction.

Implementation of an EM system may be through compliance with, and certification to ISO 14001, “Environmental Management Systems—Specification with Guidance for Use.” In general, a project’s EM system, the management program should achieve the principles noted below. These principles become specifics within the project overall ISMS.

- Assess potential environmental impacts.
- Assess legal and regulatory requirements.
- Establish an appropriate lifecycle environmental policy, including a commitment to prevention of pollution.
- Determine the legislative requirements and environmental aspects associated with project activities, products, and services.
- Develop management and employee commitment to the protection of the environment, with clear assignment of accountability and responsibility.
- Encourage environmental planning throughout the project’s lifecycle for all project activities from planning through closeout.
- Establish a disciplined management process for achieving targeted performance levels.
- Provide appropriate and sufficient resources, including training, to achieve targeted performance levels on an ongoing basis.
- Establish and maintain an emergency preparedness and response program.
- Continuously evaluate environmental performance against policy, appropriate objectives and targets, and seek improvement where appropriate.
- Establish and maintain appropriate communications with the customer and internal and external stakeholders.
- Encourage and, as appropriate, require contractors and suppliers to establish an EM system or other type of written EM process.

Environmental considerations are part of most projects, regardless of the project type (e.g., design, construction, environmental cleanup, or facility startup). The IPT needs to understand the regulatory framework for the various environmental regulations—particularly those associated with environmental cleanup. Support to the IPT would normally include support from an environmental specialist. The typical steps each project needs to complete to ensure it meets its environmental stewardship commitment are outlined in Figure 3-2.

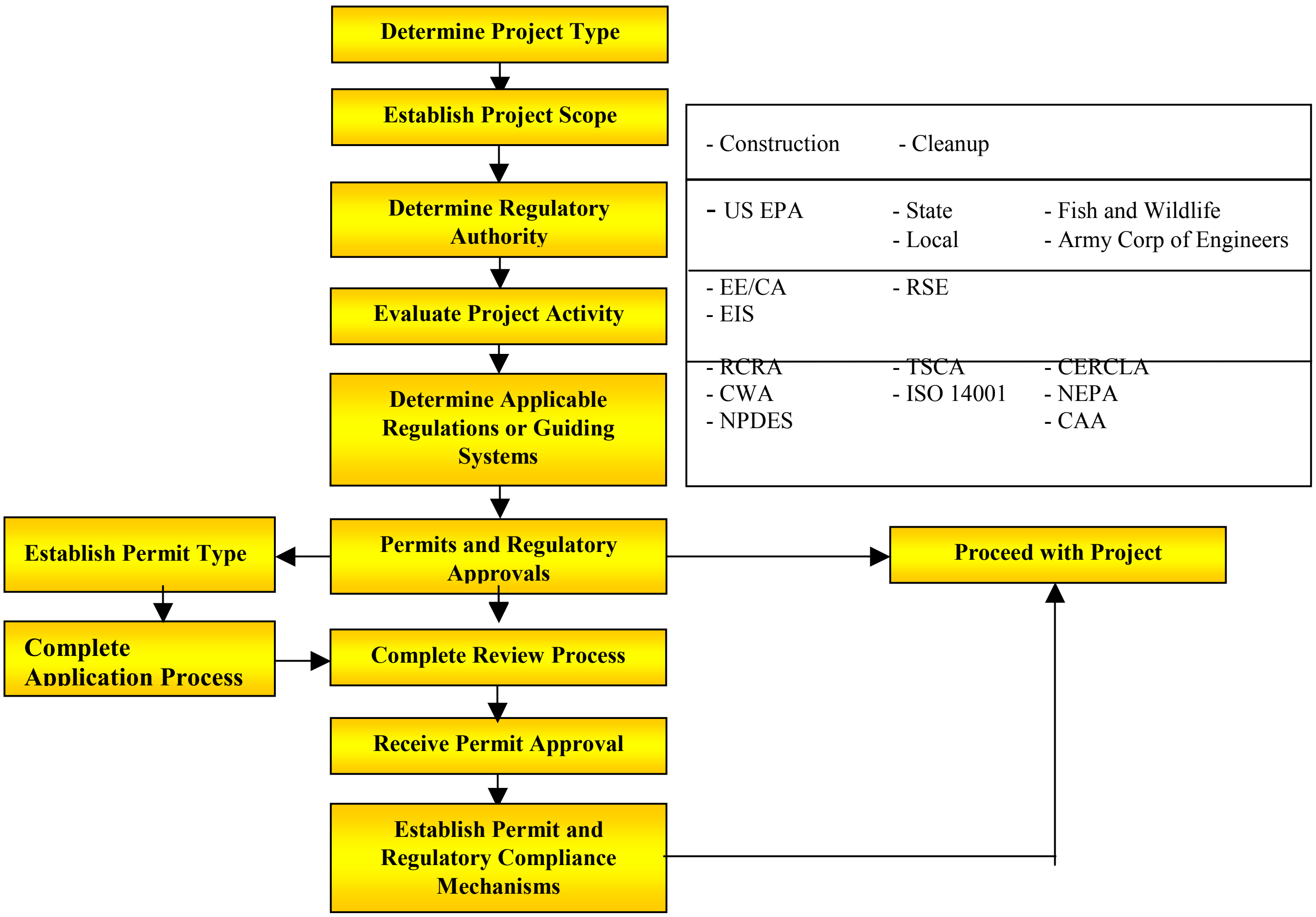

Figure 3-2. Typical Environmental Activities for DOE Projects

An example of one of the environmental regulations that may be applicable to the project is the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). CERCLA is guided by the National Oil and Hazardous Substance Pollution Contingency Plan, commonly referred to as the National Contingency Plan (NCP). This plan outlines the steps that will be followed in responding to situations in which hazardous substances, pollutants/contaminants, or oil are inadvertently released into the environment. The NCP establishes the criteria, methods, and procedures that the EPA and other Federal agencies (including DOE) are required to use to determine priority releases for long-term evaluations and response.

The NCP does not specify project cleanup levels or how a cleanup will be conducted. The NCP relies on other regulations, (e.g., RCRA, Clean Water Act [CWA], and Clean Air Act [CAA]) to provide cleanup levels and the framework for managing a CERCLA project site. Figure 3-3 outlines the CERCLA regulatory hierarchy.

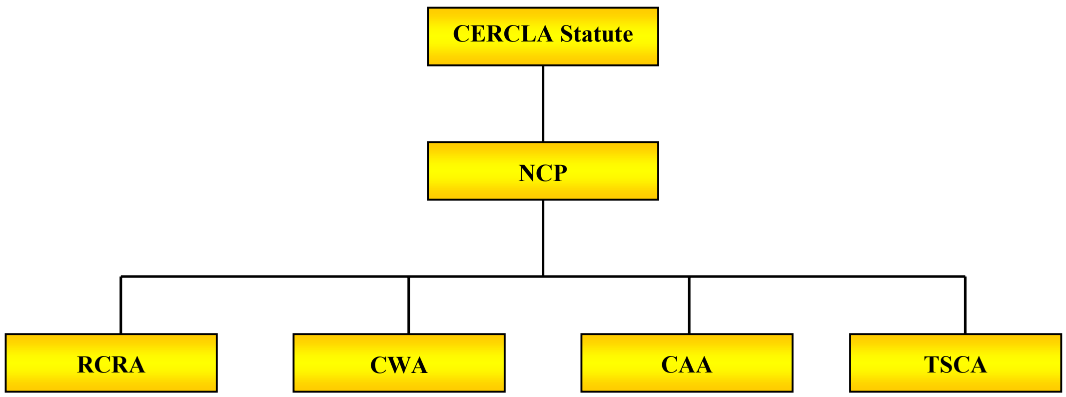

Figure 3-3. CERCLA Regulatory Hierarchy

DOE projects may have additional environmental regulations that are to be met. The NEPA process is an example of one such regulation. This process is a decision-making and planning tool for any DOE project that could have an environmental impact, not just environmental cleanup projects.

3.3 Quality Assurance

The PM is responsible to plan and implement a Quality Assurance Program (QAP) for the project and for assuring that along with safety, health, and environmental protection quality is integrated with the project. The line organizations are responsible for assuring the quality of the project. Quality Assurance (QA) begins at project conception and runs through design, development, construction, fabrication, operation, remediation, and decontamination and decommissioning (D&D). Quality affects cost, availability, effectiveness, safety, and impact on the environment. Therefore, appropriate aspects of quality assurance need to be given careful consideration during the preparation of project documentation. This is accomplished when there is a recognized need to obtain the level of product and performance quality necessary to accomplish program objectives; provide reliability and continuity of operations, commensurate with Departmental responsibility for health and safety; and for the protection of personnel, the environment, and property.

- The PM is responsible for defining and assuring that effective implementation of required QA activities be established and implemented by the contractor.
- Line management is responsible for assuring compliance with quality implementing procedures and practices.

QA is mandated through the promulgation of an Order (414.1A) and a Rule (Title 10 Code of Federal Regulations [CFR] 830.120). The Order applies to all projects and facilities, and requires that both DOE and its contractors prepare and comply with an approved QAP. Title 10 CFR 830.120 (the Rule) identifies the top-level quality assurance requirements for establishing quality assurance programs for DOE management, operating contractors, and organizations performing work at or for DOE nuclear facilities.

The Order and Rule provide the basic areas to be covered by the project QAP. For nuclear projects, 10 CFR 830.120 and its attendant Price Anderson Act Program is to be implemented. For other programs, DOE Order 414.1A is to be applied.

10 CFR 830.120 and DOE O 414.1A have the same 10 basic requirements, subdivided into three sections. Successful implementation of these criteria can be summarized as follows:

A. MANAGEMENT

- Criterion 1 – Program
  - A written QAP has been developed, implemented, and maintained.
- Criterion 2 – Personnel Training and Qualification
  - Personnel have been trained and qualified for the task assigned and training is continuing.
- Criterion 3 – Quality Improvement
  - Processes are in place to detect and prevent quality problems, control nonconforming items, identify cause and correction of quality issues, and provide for improvement.
- Criterion 4 – Documents and Records
  - Documents are prepared, reviewed, approved, and issued to specify requirements or establish designs. Records are specified, prepared, reviewed, approved, and maintained.

B. PERFORMANCE

- Criterion 5 – Work Processes
  - Work is performed to established standards and controls.
  - Items are identified and controlled for proper use.
  - Items are maintained.
  - Instruments are calibrated and maintained.
- Criterion 6 – Design
  - Sound engineering standards and principles are being used in the design.
  - Designs incorporate appropriate requirements and bases.
  - Design interfaces are identified and controlled.

- Design adequacy has been or will be verified or validated by an independent group before the design is implemented.

— Criterion 7 – Procurement

- Procured items and services meet established requirements.
- Suppliers are evaluated against specified criteria.
- Suppliers are routinely evaluated to assure continuing acceptability.

— Criterion 8 – Inspection and Acceptance

- Inspection and testing are using equipment that has been calibrated and maintained to assure acceptance and performance criteria are met.

C. ASSESSMENT

— Criterion 9 – Management Assessment

- Managers routinely assess their processes.
- Problems that hinder achievement of objectives are identified and corrected.

— Criterion 10 – Independent Assessment

- Independent assessments are planned and conducted to measure item and service quality, measure adequacy of work performed, and promote improvement.
- Independent assessments are performed by groups independent of the performers to assure the effective performance of responsibilities.
- Assessors are technically qualified and knowledgeable in the assessed areas.

3.3.1 Quality Assurance Program (QAP)

The QAP describes the overall quality management system and the project responsibility and authority for quality-related activities. The QAP covers the functional activities involved in the production of end items, products, and services.

Senior management demonstrates commitment and leadership to achieve quality through active involvement in the development and implementation of the Quality Assurance Program. Line management is responsible for assuring that line personnel are indoctrinated and trained to the requirements of the QAP Manual and the respective project procedures that implement quality requirements. Project personnel are responsible for achieving quality in the performance of their work activities.

The QAP identifies line management ownership of quality and provides for line management responsibility and involvement at all levels. It further recognizes the need to continuously assess and improve internal processes.

3.3.2 QAP Requirements

The IPT prepares a QAP at the earliest possible stage. The QAP should address all applicable elements of either the Rule or the Order. Guidance is provided in DOE G 414.1-2 as to what should be considered in preparing the QAP to meet the Order and is also appropriate guidance for the Rule. The QAP is a living document, subject to review and revision as the project grows and matures. For example, when a project selects a contractor for the design the QAP will require revision to address the methods to be used to ensure the design agency is incorporating quality and quality requirements in design activities and deliverables.

The IPT should tailor the selected standards to the requirements of the project to assure an adequate level of control is applied to all project activities. This means that the project activities to be performed should be addressed, explaining the methods used to assure each activity is appropriately controlled.

The key requirements to be considered when developing the Project Quality Assurance Program area are included in the references identified in Appendix B.

3.3.3 Program Development

Typically, projects select an appropriate industry standard and tailor that standard to meet applicable Rule and Order requirements and the project requirements. For example, a nuclear facility construction project may select the American Society of Mechanical Engineers/National Quality Assurance Standard-1 (ASME/NQA-1) as an appropriate industry standard upon which to base the QA program and develop a cross-referenced matrix between the prepared NQA-1 program and the requirements of 10 CFR 830.120. Regardless of the standard selected, a matrix of applicable project procedures to meet the selected industry standard and the Rule and Order requirements assures that all appropriate control aspects are in place. An important feature of the program is to carefully separate the project nuclear aspects from the non-nuclear features due to Price Anderson Amendment Act considerations. Tailoring of QA requirements is discussed later in this section.

The QA program matrix is composed of implementing procedures from all aspects of the project. This means that implementing procedures such as procurement procedures, engineering procedures, test procedures, safety procedures, environmental procedures, assessment procedures, quality assurance procedures, and others are identified in the matrix that makes up the project's QAP for the Project.

The Project QA organization supports the project at all levels, aiding in developing systems and procedures necessary to assure compliance with the applicable project requirements. The QA organization also provides an independent level of assurance, through audits, surveillance, and reviews, that the project, customer, and regulatory requirements are being met. As a member of the project, QA is responsible to support the project effort to complete the project on time, within budget, and within requirements.

3.3.4 Implementation

Quality program implementation occurs in phases. As early as possible (and no later than the beginning of conceptual design, the quality standard to be applied will have been selected and the QAP prepared. The QAP includes the quality program matrix identifying how applicable DOE standards will be met. The QAP and matrix identifies all of the controls required and provides details for implementing control features, including identification of those controls needing to be in place early. The remaining systems and procedures will be planned and scheduled for implementation prior to need. This means that procedures for the control of procurement activities will be developed and issued before procurement activities commence. The design control system procedures will be implemented before commencing design activities. Likewise, construction procedures need to be prepared and implemented prior to starting the construction phase.

3.3.5 Tailoring

A very important task in the development of all formal project processes, including the Project QA program, is determining where and how the quality program requirements will be applied. This "tailoring" of requirements is essential to minimizing quality cost by focusing the QA effort on the areas important to successfully meeting the users quality expectations. For example, as soon as the radiologically significant components of the facility are identified, quality program planning should commence to assure that the appropriate quality controls are applied during design, procurement, fabrication, and testing.

An essential component of tailoring quality requirements is categorizing facility systems and components. Early in the preconceptual stage, the project team should develop a method to categorize project systems, components, and activities based on such things as radiological, environmental, cost, and schedule impact. Where there are existing site categorization systems, the project should seriously consider implementing them rather than creating new systems.

3.4 Source Documents

The DOE Orders provide requirements for specific activities, such as packaging and transportation (DOE O 460.1A and 460.2), worker protection (DOE O 440.1A), etc. The specific set of applicable laws and DOE Orders, Standards, Policies, Manuals, and Guides appropriate for implementing of safety, health, environmental and quality requirements are to be defined for each project. DOE Guides and DOE Standards support implementation of the Orders. The key source documents to be considered when developing and implementing the safety, environmental, and quality portion of the project management activities are listed in Appendix B, References. Some of these source documents provide hazard, task, or facility specific requirements.

3.5 Safeguards and Security

For many DOE projects, Safeguards and Security (S&S) is an integral part of project planning and execution. S&S refers to the parameters of physical security that are built into a facility concerning access control, intrusion alarms, construction of vaults, property protection features, Operational Security (OPSEC) and even architectural surety. S&S requirements, when applicable, should be addressed early in the initial phases of a project and along with safety, quality and environmental protection, integrated throughout all project phases. The IPT should include S&S representation, if appropriate, and S&S should be confirmed and integrated by the project manager. Lifecycle cost analysis and overall system engineering should identify the requirements and costs for S&S during early project planning.

S&S should be considered and incorporated into all phases of a project, examples include:

- Preconceptual planning—draft a preliminary vulnerability assessment and initiate OPSEC considerations.
- Conceptual design should include a more detailed conceptual vulnerability assessment.
- S&S standards and requirements are incorporated into the design criteria, specifications and drawings.
- Construction and testing should address and confirm S&S design requirements.

Plans and considerations related to S&S should be included as part of the PEP and may affect other components of the PEP, such as emergency preparedness planning, communications, and procurement planning.

4 INITIATION

The project Initiation phase includes those activities and actions that occur prior to CD-0, Approve Mission Need. In terms of specific project activities, Initiation includes early planning, mission need identification, IPT organization, draft acquisition strategy, pre-acquisition design, PED funds request, etc.

Projects mature through a planned sequence of activities that begin with the identification of a mission need, evaluation of alternatives and possible solutions, and definition of a concept or identified need. They are then implemented through a process that produces the desired product or service. Portions of a project's sequence are timed to produce results that are consistent with budgetary requirements.

While projects have certain similarities as they progress from one project phase to the next, each project will also possess some unique attributes. Care is to be exercised to initiate controls and oversight commensurate with the complexity and cost of the proposed work. Management controls and oversight are necessary during every project phase, but these controls may be tailored to meet project requirements to ensure that the process effectively delivers the new materiel assets.

Initially, Sections 4.1 through 4.5 provide essential discussion on the project phases. Highlights are provided concerning inputs, activities, and deliverables as well as coverage on the Planning, Programming, Budgeting System (PPBS) and PED budget request processes. Sections 4.6 through 4.9 identify the specific processes and deliverables for project initiation.

4.1 Project Phases and Models Overview

The following project phases and models overview is provided to assist the IPT. However, projects by their very nature are unique undertakings and will generally have differences. These differences and interdependencies are to be understood and accounted for by the IPT. Project phases and sub-phases assist in understanding the timeline (i.e., phases/life cycle) of various projects. This helps in the integration of a given project timeline with the various processes and decision points required to successfully accomplish a project. To assist users of this Manual, simplified (one-line) time-phased models have been developed for each of the major project types, with additional detail for the most common project model (System Project) expanded to reflect the more realistic level of complexity. Figure 4-1 provides this more realistic, yet still somewhat simplified integration of the various sub-phases and allows a comparison with the other one-line models.